UNITED STATES COURT OF APPEALS

FOR THE NINTH CIRCUIT

CAMILLE CARSON,

Plaintiff - Appellant,

v.

DEPUY SPINE, INC., a corporation,

Defendant - Appellee.

No. 08-56698

D.C. No. 2:06-cv-07430-VBF-PLA
U.S. District Court for Central California, Los Angeles

MANDATE

The judgment of this Court, entered February 16, 2010, takes effect this date.

This constitutes the formal mandate of this Court issued pursuant to Rule 41(a) of the Federal Rules of Appellate Procedure.

FOR THE COURT:

Molly C. Dwyer
Clerk of Court

Lee-Ann Collins
Deputy Clerk

NOT FOR PUBLICATION

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MEMORANDUM*

Appeal from the United States District Court
for the Central District of California
Valerie Baker Fairbank, District Judge, Presiding

Submitted February 11, 2010**
Pasadena, California

Before: THOMAS and SILVERMAN, Circuit Judges, and BEISTLINE,*** Chief District Judge.

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* This disposition is not appropriate for publication and is not precedent except as provided by 9th Cir. R. 36-3.

** This panel unanimously finds this case suitable for decision without oral argument. See Fed. R. App. P. 34(a)(2).

*** The Honorable Ralph R. Beistline, United States District Judge for the District of Alaska, sitting by designation.

Camille Carson appeals the district court's grant of summary judgment in favor of DePuy Spine, Inc. We affirm. Because the parties are familiar with the facts and procedural history of this case, we need not recount it here.

I

The district court properly granted summary judgment on Carson's negligent manufacturing claim concerning a Charite Artificial Disc, which is manufactured and distributed by DePuy. The disc is a Class III[1] medical device regulated by the Food and Drug Administration ("FDA") under the Food, Drug, and Cosmetics Act ("FDCA"), 21 U.S.C. § 360c *et seq.* In October 2004, the FDA granted pre-market approval ("PMA") to DePuy Spine for sale and distribution of the Charite Disc in the United States.

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[1]In 1976 Congress passed the Medical Device Amendments to the FDCA. The amendments established a regulatory regime with various levels of oversight for medical devices, depending on the risks they present. Class I, which includes such devices as elastic bandages and examination gloves, is subject to the lowest level of oversight: "general controls," such as labeling requirements. 21 U.S.C. § 360c(a)(1)(A). Class II, which includes such devices as powered wheelchairs, is subject to "special controls," such as performance standards and postmarket surveillance measures. 21 U.S.C. § 360c(a)(1)(B). Class III, which includes replacement heart valves and pacemaker pulse generators, receives the most federal oversight. The amendments established a rigorous regime of pre-market approval for new Class III devices, and the FDA spends an average of 1200 hours reviewing each application. *Medtronic Inc. v. Lohr*, 518 U.S. 470, 477 (1996). The agency approves the labeling of the product, and is free to impose device-specific restrictions by regulation. 21 U.S.C. § 360j(e)(1).

To prove a negligent manufacturing claim under California law, a plaintiff must first show that the product as delivered departed from the governing specifications. A manufacturing defect occurs when the product "differs from the manufacturer's intended result or from other ostensibly identical units from the same product line." *Barker v. Lull Engineering Co.*, 20 Cal. 3d 413, 429 (1978). If a product meets the design specifications applicable at the time of manufacture, there is no manufacturing defect. *In re Coordinated Latex Glove Litigation*, 99 Cal. App. 4th 594, 612-13 (2002).

In addition, because the product received pre-market approval from the FDA, Carson must prove the variation in her particular disk was from specifications approved by the FDA. 21 U.S.C. § 360K; *Riegel v. Medtronic, Inc.*, 552 U.S. 312 (2008). Finally, as with any tort claim, the plaintiff must prove the alleged defect caused her injury. *Soule v. GM Corp.*, 8 Cal. 4th 548, 560 (1994).

The district court properly concluded that Carson did not present sufficient evidence creating a genuine issue of fact as to any of the elements of a manufacturing defect claim. The uncontroverted testimony of Dr. Kropf reveals that the disk did not have any visible problems upon implementation, that Carson developed a spinal condition where her vertebrae began moving in a fashion that put extreme stress on the disk, and likely caused the polyethylene to deform in

response to the stressors, and that he himself broke the disk while removing it during the revision surgery in order to complete a spinal fusion that addressed Carson's spinal condition. Carson disputes Kropf's credibility; however, a "party opposing summary judgment may not simply question the credibility of the movant to foreclose summary judgment." *Far Out Productions, Inc. v. Oskar*, 247 F.3d 986, 997 (9th Cir. 2001). Carson did not cite any specific FDA pre-marketing standard or specification that had been violated by any such purported defect.

We see no abuse of discretion in the district court's denial of Carson's request in briefing that it reconsider its manufacturing defect ruling, citing *Riegel v. Medtronic, Inc.*, 552 U.S. 312 (2008). The district court declined to entertain the request because it was untimely and not properly presented. The district court did not abuse its discretion in rejecting the informal reconsideration request on procedural grounds.

In sum, DuPuy's expert testimony was not controverted; no contrary evidence was tendered; and Carson did not identify any federal standard that DuPuy violated in the manufacture of the product. The district court did not abuse its discretion in declining to revisit its ruling. Therefore, we affirm the district court's grant of summary judgment in favor DePuy on the manufacturing defect claim.

II

The district court did not err in granting summary judgment on Carson's claim that DePuy was negligent in allegedly promoting off-label use for its product.

Drugs and medical devices are approved or cleared by the FDA for marketing with labels describing the uses and the patient conditions which have been reviewed in the approval or clearance process. Any use by a physician which differs from the use described in the label or from the patient conditions described in the label is called "off-label."

The FDCA expressly protects off-label use: "Nothing in this chapter shall be construed to limit or interfere with the authority of a health care practitioner to prescribe or administer any legally marketed device to a patient for any condition or disease within a legitimate health care practitioner-patient relationship." 21 U.S.C. § 396. In addition, the Supreme Court has emphasized that off-label use by medical professionals is not merely legitimate but important in the practice of medicine. *Buckman Co. v. Plaintiffs' Legal Comm.*, 531 U.S. 341, 350 (2001).

The FDA has adopted regulations that limit a drug or device manufacturer's ability to promote a drug or device for off-label use. Therefore, while doctors may use a drug or device off-label, the marketing and promotion of a Class III device

for an unapproved use violates Section 331 of the FDCA. 21 U.S.C. § 331. However, a manufacturer is not liable merely because it sells a device with knowledge that the prescribing doctor intends an off-label use.

Because the FDCA prohibits private enforcement, 21 U.S.C. § 337, Carson asserts a state law negligence *per se* theory predicated on violation of federal law. In California, negligence *per se* is not a separate cause of action but is the application of an evidentiary presumption provided by Cal. Evid. Code § 669. *Quiroz v. Seventh Avenue Center*, 140 Cal. App. 4th 1256, 1285-86 (Cal. 2006). In California, there are four elements required to establish a viable negligence *per se* theory: (1) the defendant violated a statute or regulation; (2) the violation caused the plaintiff's injury; (3) the injury resulted from the kind of occurrence the statute or regulation was designed to prevent; and (4) the plaintiff was a member of the class of persons the statute or regulation was intended to protect. *Alejo v. City of Alhambra,* 75 Cal.App.4th 1180, 1184-1185 (Cal.App. 1999).

The district court correctly concluded that Carson had failed to present sufficient evidence to create a genuine issue as to two of the elements: violation of federal law and causation. A careful review of the record confirms the district court's conclusion. There is no evidence in the record to support Carson's claim that DePuy illegally promoted an off-label use of the Charite Disc, that Dr. Kropf

was influenced by such promotion, or that the off-label use of the disk caused Carson's injury. In fact, the only evidence in the record is to the contrary. Similarly, the record is devoid of evidence of causation. Therefore, the district court appropriately granted summary judgment.

AFFIRMED.

United States Court of Appeals for the Ninth Circuit

Office of the Clerk
95 Seventh Street
San Francisco, CA 94103

Information Regarding Judgment and Post-Judgment Proceedings
(December 2009)

Judgment

- This Court has filed and entered the attached judgment in your case. Fed. R. App. P. 36. Please note the filed date on the attached decision because all of the dates described below run from that date, not from the date you receive this notice.

Mandate (Fed. R. App. P. 41; 9th Cir. R. 41-1 & -2)

- The mandate will issue 7 days after the expiration of the time for filing a petition for rehearing or 7 days from the denial of a petition for rehearing, unless the Court directs otherwise. To file a motion to stay the mandate, file it electronically via the appellate ECF system or, if you are a pro se litigant or an attorney with an exemption from using appellate ECF, file one original motion on paper.

Petition for Panel Rehearing (Fed. R. App. P. 40; 9th Cir. R. 40-1)
Petition for Rehearing En Banc (Fed. R. App. P. 35; 9th Cir. R. 35-1 to -3)

(1) A. Purpose (Panel Rehearing):

- A party should seek panel rehearing only if one or more of the following grounds exist:
  - ▶ A material point of fact or law was overlooked in the decision;
  - ▶ A change in the law occurred after the case was submitted which appears to have been overlooked by the panel; or
  - ▶ An apparent conflict with another decision of the Court was not addressed in the opinion.
- Do not file a petition for panel rehearing merely to reargue the case.

B. Purpose (Rehearing En Banc)

- A party should seek en banc rehearing only if one or more of the following grounds exist:

- ▶ Consideration by the full Court is necessary to secure or maintain uniformity of the Court's decisions; or
- ▶ The proceeding involves a question of exceptional importance; or
- ▶ The opinion directly conflicts with an existing opinion by another court of appeals or the Supreme Court and substantially affects a rule of national application in which there is an overriding need for national uniformity.

(2) Deadlines for Filing:

- A petition for rehearing may be filed within 14 days after entry of judgment. Fed. R. App. P. 40(a)(1).
- If the United States or an agency or officer thereof is a party in a civil case, the time for filing a petition for rehearing is 45 days after entry of judgment. Fed. R. App. P. 40(a)(1).
- If the mandate has issued, the petition for rehearing should be accompanied by a motion to recall the mandate.
- *See* Advisory Note to 9th Cir. R. 40-1 (petitions must be received on the due date).
- An order to publish a previously unpublished memorandum disposition extends the time to file a petition for rehearing to 14 days after the date of the order of publication or, in all civil cases in which the United States or an agency or officer thereof is a party, 45 days after the date of the order of publication. 9th Cir. R. 40-2.

(3) Statement of Counsel

- A petition should contain an introduction stating that, in counsel's judgment, one or more of the situations described in the "purpose" section above exist. The points to be raised must be stated clearly.

(4) Form & Number of Copies (9th Cir. R. 40-1; Fed. R. App. P. 32(c)(2))

- The petition shall not exceed 15 pages unless it complies with the alternative length limitations of 4,200 words or 390 lines of text.
- The petition must be accompanied by a copy of the panel's decision being challenged.
- An answer, when ordered by the Court, shall comply with the same length limitations as the petition.
- If a pro se litigant elects to file a form brief pursuant to Circuit Rule 28-1, a petition for panel rehearing or for rehearing en banc need not comply with Fed. R. App. P. 32.

- The petition or answer must be accompanied by a Certificate of Compliance found at Form 11, available on our website at under *Forms*.
- You may file a petition electronically via the appellate ECF system. No paper copies are required unless the Court orders otherwise. If you are a pro se litigant or an attorney exempted from using the appellate ECF system, file one original petition on paper. No additional paper copies are required unless the Court orders otherwise.

Bill of Costs (Fed. R. App. P. 39, 9th Cir. R. 39-1)

- The Bill of Costs must be filed within 14 days after entry of judgment.
- See Form 10 for additional information, available on our website at under *Forms*.

Attorneys Fees

- Ninth Circuit Rule 39-1 describes the content and due dates for attorneys fees applications.
- All relevant forms are available on our website at under *Forms* or by telephoning (415) 355-7806.

Petition for a Writ of Certiorari

- Please refer to the Rules of the United States Supreme Court at

Counsel Listing in Published Opinions

- Please check counsel listing on the attached decision.
- If there are any errors in a published opinion, please send a letter **in writing within 10 days** to:
  - West Publishing Company; 610 Opperman Drive; PO Box 64526; St. Paul, MN 55164-0526 (Attn: Kathy Blesener, Senior Editor);
  - and electronically file a copy of the letter via the appellate ECF system by using "File Correspondence to Court," or if you are an attorney exempted from using the appellate ECF system, mail the Court one copy of the letter.

Form 10. Bill of Costs ..... *(Rev. 12-1-09)*

United States Court of Appeals for the Ninth Circuit

BILL OF COSTS

Note: If you wish to file a bill of costs, it MUST be submitted on this form and filed, with the clerk, with proof of service, within 14 days of the date of entry of judgment, and in accordance with 9th Circuit Rule 39-1. A late bill of costs must be accompanied by a motion showing good cause. Please refer to FRAP 39, 28 U.S.C. § 1920, and 9th Circuit Rule 39-1 when preparing your bill of costs.

_____ v. _____ 9th Cir. No. _____

The Clerk is requested to tax the following costs against: _____

Cost Taxable under FRAP 39, 28 U.S.C. § 1920, 9th Cir. R. 39-1	REQUESTED Each Column Must Be Completed				ALLOWED To Be Completed by the Clerk			
	No. of Docs.	Pages per Doc.	Cost per Page*	TOTAL COST	No. of Docs.	Pages per Doc.	Cost per Page*	TOTAL COST
Excerpt of Record			$	$			$	$
Opening Brief			$	$			$	$
Answering Brief			$	$			$	$
Reply Brief			$	$			$	$
Other**			$	$			$	$
			TOTAL:	$			TOTAL:	$

* Costs per page may not exceed .10 or actual cost, whichever is less. 9th Circuit Rule 39-1.

** Other: Any other requests must be accompanied by a statement explaining why the item(s) should be taxed pursuant to 9th Circuit Rule 39-1. Additional items without such supporting statements will not be considered.

Attorneys' fees **cannot** be requested on this form.

Continue to next page.

Form 10. Bill of Costs - *Continued*

I, _____, swear under penalty of perjury that the services for which costs are taxed were actually and necessarily performed, and that the requested costs were actually expended as listed.

Signature _____

("s/" plus attorney's name if submitted electronically)

Date _____

Name of Counsel: _____

Attorney for: _____

(To Be Completed by the Clerk)

Date _____ Costs are taxed in the amount of $ _____

Clerk of Court

By: _____, Deputy Clerk